BIONIX®

B4000
Bed System Measurement Device

| PROBLEM

Due to increased life-threatening entrapment associated with hospital bed systems, the FDA & HBSW issued specific guidelines (Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment) which assesses entrapment risks associated with hospital bed systems.

| SOLUTION

The B4000 Bed System Measurement Device, created by the Hospital Bed Safety Workgroup, is the only validated tool that test to the FDA's Hospital Bed System Dimensional and Assessment Guide document.

| RESULTS

The B4000 and its easy to read pass/fail zones, allows a two-person team to test the 4 critical zones of a bed system in just 15 minutes providing documentable results that comply with CMS Guidance.

4 CRITICAL ENTRAPMENT ZONES

Did you know?

- There are four critical entrapment zones that can cause injury or death.
- Safety Hazards Related to Bed Rail use have been Realized since 1990
- Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment issued on March 10, 2006 by FDA. (View document here.)
- Hospital Bed Safety Workgroup (HBSW) Developed Bed Safety Entrapment Kit which includes the B4000

F-Tag 909 pertains to use of bedrails and regular inspection of the bed system

CMS takes enforcement actions when a facility is not in Compliance with Bed Rail Systems as stated by the Medicare and Medicaid Guidelines. Identified as area of concern, possible immediate jeopardy.

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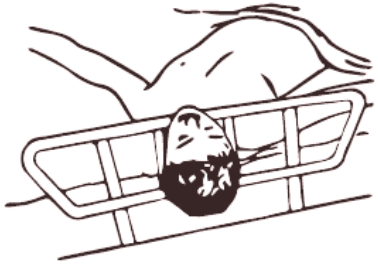
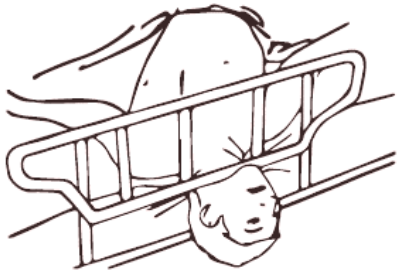
Sources:
. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm123676.htm
. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm164366.htm
. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/hospitalbeds/default.htm

| ZONE 1



| ZONE 2



| ZONE 3

| ZONE 4

| ZONE 1

Within the bed rail.

| ZONE 2

Between the bottom of the rail and the top of the mattress and between rail supports.

| ZONE 3

Between the outside edge of the mattress and the inside of the side rail.

| ZONE 4

Between the top of the compressed mattress and the bottom of the rail, at the end of the rail.

B4000 Bed System Measurement Device

Product Chart

Features & BENEFITS	The B4000 and its easy to read pass/fail zones, allows a two-person team to test the 4 critical zones of a bed system in just 15 minutes providing documentable results that comply with CMS regulations.
Quick Validation	• 15 minutes to complete (two-person team)
Tests Compliance to Critical Entrapment Areas	Tests Performed • Zone 1 - Within the bed rail itself • Zone 2 - Between the bottom of the rail & the top of the mattress & between the rail supports. • Zone 3 - Between the outside edge of the mattress & inside of the side rail • Zone 4 - Between the top of the compressed mattress & bottom of the rail at the end of the rail
Portable Device	• Includes carrying case for easy transport & storage
Easy to Read	• Color coded Pass/Fail indicators located on the device
Easily Record Test Results	• Includes preformatted testing sheets to quickly & easily record test results
Only Device to Test to FDA Guidance Standards	✓

B4000 Product Chart

- Download here

Standardizing Procedures & Documentation Across Facilities

Facilities are required to conduct regular inspection of all bed frames, mattresses and bed rails as part of a regular maintenance program. When rails and mattress are purchased separately from the frame, the facility must ensure all are compatible.

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Facility May Be Required to Show Compliance of

A regular bed maintenance program

Proper fit of the mattress to the bed frame

Proper installation of bed rail according to manufacturer's requirements to entrapment zones

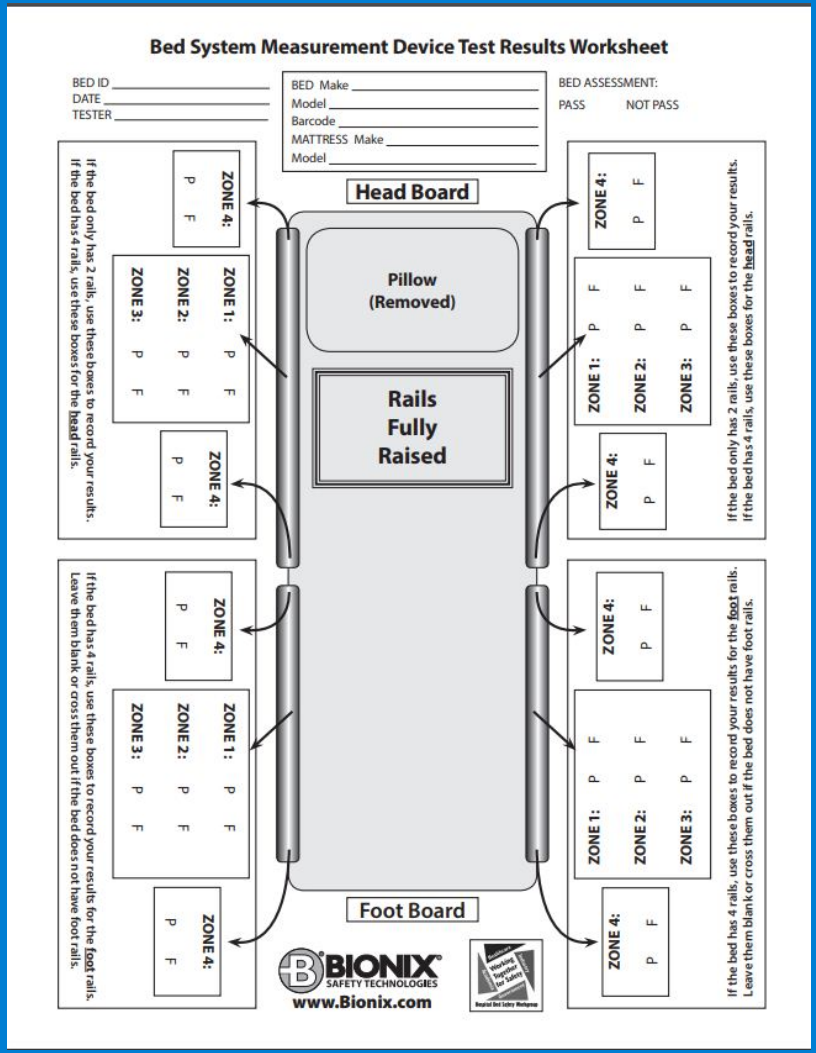
Best Practices | Testing

1. Evaluate the residents need for assist devices and side rails. (F700)

2. Test when a modification is made to assist devices and side rails.

3. Test according to manufacturers requirements.

Reduce Corporate and Facility Risk by Standardizing Testing Procedures and Practices.



HARDWARE INCLUDED

- Cone and Cylinder Tool
- Scale
- Safety Strap
- User's Guide
- Record-able Compliance Documents
- USB Drive
- Storage Briefcase

WEIGHT

- In Use: 15 lbs.
- In Storage: 27 lbs.

Bionix Development Corporation

Warranty

One -Year on all parts and labor

Guarantee

30-Day limited money back

Calibration

Required annually on the scale

Resources

Documentation - Click title to view

1. B4000 Bed System Measurement Device Sell Sheet
2. B4000 Bed System Worksheet
3. Calibration Information
4. Warranty Information

Product Videos - Click title to view video

1. Intro - B4000 Bed System Measurement Device
2. Testing Zone 1
3. Testing Zone 2
4. Testing Zone 3
5. Testing Zone 5

Assemble and Disassemble the Cone and Cylinder Tool

To disassemble:
1. Turn the knob to loosen and remove the connection shaft.
2. Pull the cylinder from the cone.

Figure 1: Disassembly and assembly of the cone and cylinder tool.

To assemble:
1. Align the red and green areas of the cone and cylinder.
2. Insert the pins of the cone into the cylinder.
3. Insert the connection shaft and turn the knob to tighten.

Spring Scale

Use the spring scale to apply 12 lbs of force to the cone in Tests 1 and 2. At the small end of the cone tool, insert the scale hook into the metal loop. Pull the scale slowly until the needle points to 12 lbs.

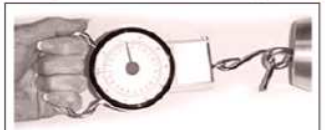


Figure 2: Use of spring scale.

Considerations for all Tests

- Bed Occupancy: For ease of mattress movement and measurement, the patient should not be in the bed during the measurement procedures.
- Bed Height: To avoid unnecessary bending or back strain, put the bed at a comfortable working height position.
- Bed Wheels: To prevent movement of the bed during testing, lock the wheels.

- Linens/Sheets: Assess the bed with sheets in place for typical patient care. Remove any pillows.
- Infection Control: To avoid cross-contamination, disinfect the assessment tools each time a different bed is measured.
- Personal Safety: To avoid injury, use care when pulling the tool through openings in the bed rails. If the tool suddenly pulls through, you could lose your balance and fall. Always use the safety strap to keep the tool from injuring your feet if it falls.
- Borderline Decision: For some tests, it may not be clear whether the bed system passes or fails the test. Testers can get different results for the same bed system. This is because mattresses vary in softness and people handle tools slightly differently. If a test is a close call, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that it was a close call.
- Order of Tests: Do the tests in any order you wish, as long as you do all of the tests on all of the rails.
- Intermediate Rail Position: Some rails have an intermediate stopping position or a high and low locking position. Follow the individual test instructions, which may require testing the rails at both positions.

Test Methods

Zone 1: Potential head entrapment within the rail

The tools needed to do this test include the cone with safety strap and spring scale.
Prepare for Test 1:
1. Lock the wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.

Do Test 1:
1. Attach the safety strap of the cone to the rail being tested. Make sure the strap is short enough to keep the tool from injuring your feet if it falls.

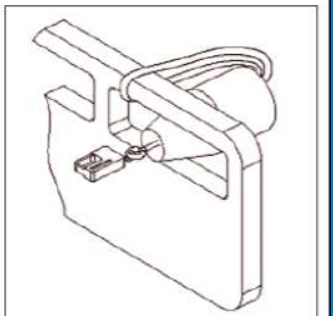


Figure 3: Test 1, within rail.

2. From inside the rail, insert the cone, small end first, into the largest opening in the rail. Try to pull the tool through the space (figure 3).
3. If the tool does not pull through freely, attach the spring scale to the end of the cone, and try to pull the tool through the rail by pulling on the attached spring scale using 12 lbs. of force. Use care when pulling. If the tool suddenly pulls through the opening, you may lose your balance and fall, or the tool may fall on you.
4. Repeat steps 2 and 3 to check all other openings within the same rail.
5. Interpret test result and record the results on the data sheet.

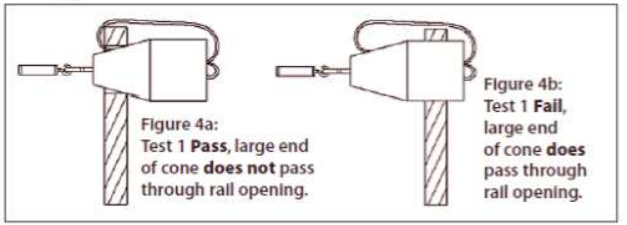


Figure 4a: Test 1 **Pass**, large end of cone **does not** pass through rail opening.

Figure 4b: Test 1 **Fail**, large end of cone **does** pass through rail opening.

Interpret Test 1 Results:
If the large end of the cone does not pass through any of the openings, this space passes the test (figure 4a).

If the large end of the cone does pass through any of the openings, this space fails the test (figure 4b).
If a test is a close call, and you have trouble deciding whether the bed system passes or fails, make your best decision and 3 mark the result with an asterisk (*) next to your answer to show that it was a close call.

Repeat Test 1:
On the other rails: Repeat the test for all other rails on the bed.

Zone 2: Potential head entrapment between the bottom of the rail and the top of the compressed mattress, and between the rail supports or next to a single support.

The tools needed to do this test include the cone with safety strap and spring scale.

Prepare for Test 2:
1. Lock the wheels.
2. Put the bed in the flat, horizontal position. Fully raise all bed rails.
3. Put the bed at a comfortable working height position.

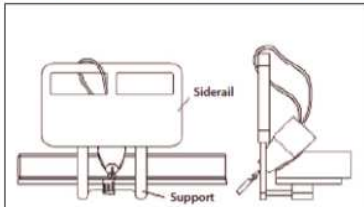


Figure 5a: Test 2, between rail and top of compressed mattress.

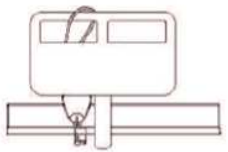


Figure 5b: Test 2, for single support.

Do Test 2:
1. Firmly push the mattress away from the rail being measured until it stops.
2. Identify the space where the test will be done (see Figure(s) 5a and 5b).
3. Raise and lower the head and foot sections of the bed. If the

spaces where the test will be done don't change as the bed moves, the test will be done in the flat position.

a. If the space changes when the head and foot sections are raised and lowered, the test will be done in the bed position where the space is the largest

4. Attach the safety strap of the cone to the rail being tested. Make sure the strap is short enough to keep the tool from injuring your feet if it falls.
5. From the inside of the rail, insert the cone, small end first, into the gap between the mattress and the lower edge, between the rail supports. Let the cone compress the mattress. Do not force the cone into the area.
6. Attach the spring scale to the loop on the cone.
7. Pull on the spring scale with 12 lbs of force at any angle that increases the chances of the cone going through the space. Use care when pulling. If the tool suddenly pulls through the opening, you may lose your balance and fall, or the tool may fall on you. Observe whether the large end of the cone passes through the opening.
8. Record the results on the data sheet.

Interpret Test 2 Results:
If the large end of the cone does not pass through the opening, this space passes the test (figure 6a).

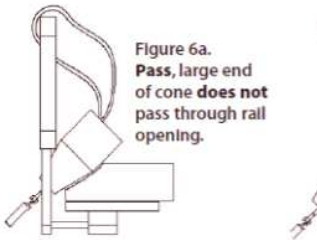


Figure 6a. **Pass**, large end of cone **does not** pass through rail opening.

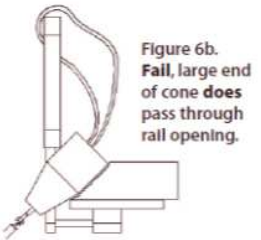


Figure 6b. **Fail**, large end of cone **does** pass through rail opening.

If the large end of the cone does pass through the opening, this space fails the test (figure 6b).

If a test is a close call, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that it was a close call.

Repeat Test 2:
On the same rail: If the rail has intermediate locking positions, do the test for every intermediate position.
On the other rails: Do the test for all other rails on the bed, including intermediate and raised positions.

Zone 3: Potential head entrapment between the edge of the mattress and the inside of the rail.

The tools needed for this test include the cone with safety strap.

Prepare for Test 3:
1. Lock the wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.

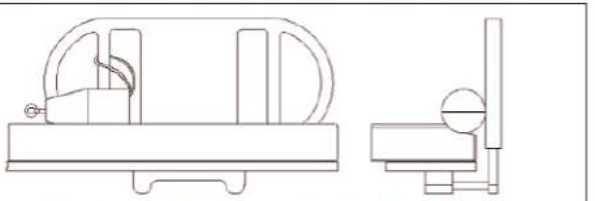


Figure 7a: Test 3, between mattress and inside of rail.

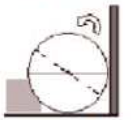


Figure 7b: Test 3, turning the cone.

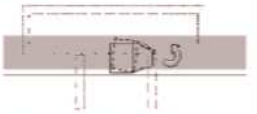


Figure 7c: Test 3, tilting cone.

Do Test 3:

1. Firmly push the mattress away from the rail being measured until it stops.
2. Put the cone near the rail being tested and attach the safety strap. Make sure the strap is short enough to prevent the tool from injuring your feet if it falls.
3. Put the cone horizontally in the gap. Do not push the tool down into the gap (figure 7a).
4. Turn the cone until the line on the end is horizontal (figure 7b).
5. Let the cone sink into the space by its own weight. If the cone is tilted, use one hand to gently level it (figure 7c). Do not push the tool down into the gap. Note: If a mattress stop, rail support, or other structure keeps the cone from sinking in the gap, put the cone tool at a different location along the rail where there is no interference.
6. Determine whether the cone's center sinks completely below the surface of the mattress.
7. Interpret test result and record the results on the data sheet.

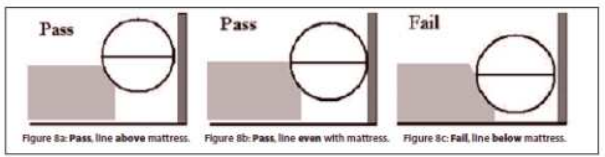


Figure 8a: **Pass**, line **above** mattress. Figure 8b: **Pass**, line **even** with mattress. Figure 8c: **Fail**, line **below** mattress.

Interpret Test 3 Results:
If the line across the flat end of the cone is above or even with the surface of the mattress, the space passes the test (figure 8a and 8b). If the line across the flat end of the cone is below the top surface of the mattress, the space fails the test (figure 8c).

If a test is a close call, and you have trouble deciding whether the bed system passes or fails, make your best decision and

mark the result with an asterisk (*) next to your answer to show that it was a close call.

Repeat Test 3:
On the same rail: If the rail has any intermediate positions, do the test at every intermediate position.
On the other rails: Do the test for all other rails on the bed, including the intermediate positions.

Zone 4: Potential neck entrapment between the top of the compressed mattress and the bottom of the rail at the end of the rail.

The tools needed for this test include the assembled cone and cylinder with safety strap.

Prepare for Test 4:
1. Lock the wheels.
2. Put the bed in the flat, horizontal position.
3. Fully raise all bed rails.
4. Put the bed at a comfortable working height position.
5. Do the test on the end of the rail (figure 9). Test the rails in any order you choose. If the bed has split rails, you may need to lower the rail next to the one being measured to make room for the tools.

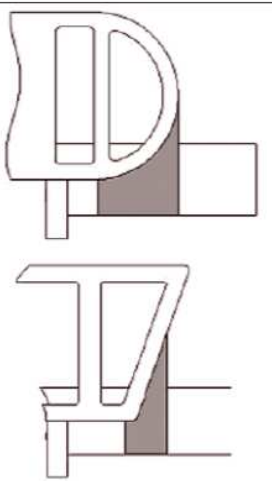


Figure 9: Test 4, between the rail and mattress, under the rail at the end of the rail.

Do Test 4:
1. Firmly push the mattress away from the rail being tested until it stops.
2. Attach the safety strap of the cone tool to the rail being tested.
3. Just beyond the end of the rail, rest the cone portion of the cone and cylinder tool on the mattress. **Note: If the cylinder tool cannot fit into an area between the head or footboard and the end of a rail, the space passes.**
4. Position the tool so that the base of the cone is flush or even with the edge of the mattress (figure 10a).

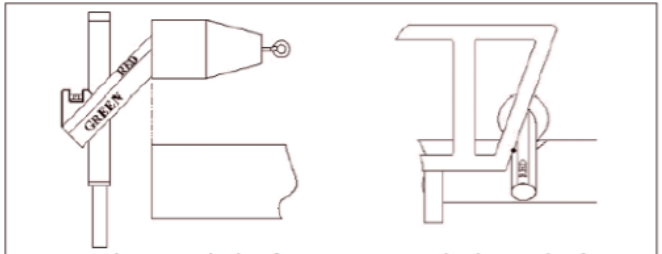


Figure 10a. Align cone with edge of mattress. Figure 10b. Observe color of contact.

5. Slide the cone and cylinder towards the rail until it touches the rail or support and let the weight of the cone compress the mattress (figure 10b).
6. Hold the cylinder section and use the level on the end of the cylinder to keep the cone level.
7. If the cylinder slides completely under the rail, this space fails. If the cylinder touches the rail, observe the color of contact: Red fails; Green passes (figure 11).
8. Interpret test result and record the results on the data sheet.

Interpret Test 4 Results:
If the cylinder touches the rail in the green area, the space passes (figure 11a).

If the cylinder touches the rail in the red area, the space fails (figure 11b).

If the cylinder passes completely under the rail without touching the rail, the space fails (figure 11c).

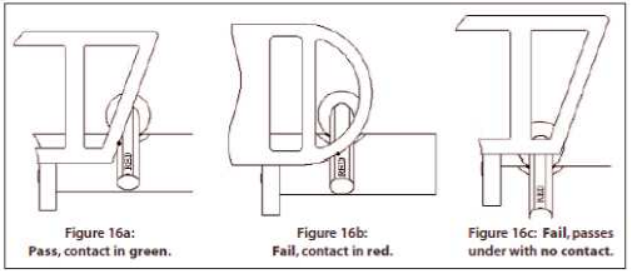


Figure 16a: Pass, contact in green.

Figure 16b: Fail, contact in red.

Figure 16c: Fail, passes under with no contact.

If the cylinder tool cannot fit into an area between the head or footboard and the end of a rail, the space passes.

If a test is a close call, and you have trouble deciding whether the bed system passes or fails, make your best decision and mark the result with an asterisk (*) next to your answer to show that it was a close call.

Repeat Test 4:
On the same rail: If the rail has any intermediate positions, do the test at every intermediate position.

On the other rails: Do all steps of test 4 for both ends of all other rails on the bed, including the intermediate positions.